REMARKS

The present communication responds to the Office Action of August 19, 2008, in which the Examiner rejected claims 1-6, 8, 9, 12, 13, 17 and 19 and objected to the specification. Claims 6, 9 and 12 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent 6,575,939 ("Brunel"). Claim 13 was rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent 6,258,068 ("Kirchhofer et al."). Claims 17 and 19 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent 4,444,560 ("Jacklich"). Claims 1-5 were rejected under 35 U.S.C. § 103(a) as unpatentable over Jacklich in view of U.S. Patent 5,433,352 ("Ronvig"). Claim 8 was rejected under 35 U.S.C. § 103(a) as unpatentable over Jacklich in view of Ronvig and further in view of U.S. Patent 4,850,967 ("Cosmai").

Claims 1, 6 and 17 have been amended. No new subject matter has been added to the claims. Support for the amended claims can be found in general throughout the specification and in particular, for example, in FIGS. 1, 2a, 2b and 2e.

The claim rejections are traversed in view of the amendments and for at least the reasons articulated below.

Reconsideration is requested.

Specification

The disclosure was objected to for failure to provide proper antecedent basis for the claimed subject matter.

In the specification, paragraphs 41, 43, 44, 49, 50 and 51 have been amended to recite a one-piece lever 7. Support for the amendment to the specification can be found in FIGS. 1, 2a, 2b and 3.

Additionally, paragraph 45 was amended to recite a releasing element 50, projecting radially outward from inside the housing. Support for the amendment to the specification can be found in FIG. 2e.

Please note that paragraphs 45, 50 and 51 were also previously amended in the response to the Office Action of September 14, 2006, as shown in Replacement Pages 13-16.

Withdrawal of the objections to the specification is requested.

Rejection under 35 U.S.C. § 102

The rejections are traversed for at least the following reasons.

Brunel

Claims 6, 9 and 12 were rejected under 35 U.S.C. § 102(e) as anticipated by Brunel.

Claim 6 has been amended to clarify that the releasing element projects radially outward from inside the casing and extends through an opening in the casing of the injection device.

Brunel discloses a device for automatically injecting a dose of a medicinal product. The device includes a sleeve 12 provided with a trigger 15 in its peripheral wall. (*Brunel, col. 6, lines 1-4*). The trigger 15 has a longitudinal bar 15a oriented in the direction of the rear end of the sleeve 12 and is adapted so that when pressed by a finger, the transverse member 15b retracts inside the sleeve. (*Brunel, col. 6, lines 5-10*). According to Brunel, "sleeve 12 is, in addition, provided with a "trigger" delimited by a slot 17 provided in its peripheral wall, and adapted so as to pivot longitudinally and to retract partially inside the said sleeve under the effect of manual pressure. (*Brunel, col. 6, lines 1-4*).

Brunel does not disclose that the releasing element projects radially outward from inside the casing and extends through an opening in the casing of the injection device as recited in amended claim 6. Instead, the trigger 15 is formed integrally on the sleeve 12 in a longitudinal direction. The slot 17 of Brunel is located on one end of the trigger 15. Brunel's trigger 15 does not project radially outward from inside the casing, the trigger 15 retracts only partially inside the sleeve 12 via the slot 17, since trigger 15 is formed integrally on the sleeve 12.

The trigger 15 has a corrugated upper face provided with transverse ribs such as 16 projecting with respect to the peripheral wall of the sleeve 12. (*Brunel, col. 6, lines 10-12 and FIGS. 1 and 2*). However, these ribs 16 do not project radially outward from inside the casing, and extend through an opening in the casing of the injection device. The ribs merely give corrugation to the upper face of the trigger 15.

Therefore, there are structural differences between Brunel and amended claim 6.

Claims 9 and 12 depend directly or indirectly from claim 6 and are patentable over Brunel for at least those reasons set forth above with respect to amended claim 6.

Reconsideration and withdrawal of the § 102 rejection of claims 6, 9 and 12 are requested.

Kirchhofer et al.

Claim 13 was rejected under 35 U.S.C. § 102(b) as anticipated by Kirchhofer et al.

Claim 13 is directed to an injection device for administering a fluid product comprising, in part, "a needle protector, wherein the needle protector comprises a sleeve arranged on one of the holder for the product container or the product container such that the sleeve is shiftable in a longitudinal direction with respect to the holder for the product container or the product container . . . ."

Kirchhofer et al. discloses an injection device with a container holder 30 connected to the front housing sleeve 7 non-shiftably in relation to the front housing sleeve 7. (*Kirchhofer et al., col. 5, lines 19-21*). Kirchhofer et al. also discloses a needle safety sleeve 10, an intermediate sleeve 20 and a releasing sleeve 35. (*Kirchhofer et al., col. 5, lines 14-15 and 29, and FIG. 1*).

Kirchhofer et al. does not disclose a needle protector, wherein the needle protector comprises a sleeve arranged on one of the holder for the product container or the product

container such that the sleeve is shiftable in a longitudinal direction with respect to the holder for the product container or the product container as recited in claim 13.

It is the intermediate sleeve 20 that is arranged in an annular gap between the container holder 30 and the front housing sleeve 7, and this intermediate sleeve 20 is displaceable in relation to the front housing sleeve 7 and the container holder. (*Kirchhofer et al., col. 5, lines 15-26*). In Kirchhofer et al. there is an intermediate sleeve 20 and also a needle safety sleeve 10, and it is the intermediate sleeve 20 which is arranged on the container holder 30.

Furthermore, Kirchhofer et al. discloses that the needle safety sleeve 10, together with the intermediate sleeve 20 and the releasing sleeve 35, in relation to the housing sleeves 4 and 7 and the container holder 30 with the container 1, can be shifted back against the forward direction. (*Kirchhofer et al., col. 6, lines 1-5*). However, the needle safety sleeve 10 of Kirchhofer et al. is a different sleeve than the intermediate sleeve 20 of which is arranged on the container holder 30. Therefore, there are structural difference between Kirchhofer et al. and claim 13.

Reconsideration and withdrawal of the § 102 rejection of claim 13 are requested.

Jacklich

Claims 17 and 19 were rejected under 35 U.S.C. § 102(b) as anticipated by Jacklich.

Amended claim 17 is directed to an injection device comprising "a casing, operating means pivotable in a radial direction relative to the device about a fulcrum arranged laterally on the device, wherein the operating means includes a one-piece lever comprising a lever arm and a protrusion, the protrusion co-operative with dispensing means via a surface oblique with respect to a longitudinal axis of the device, such that the dispensing means is moved in an axial direction relative to the device by pivoting the operating means; and a releasing element for releasing a dosage amount to be dispensed by the injection device, wherein the releasing element projects radially outward from inside the casing through an opening in the casing of the injection device, and dimensions of the opening limit movement of the releasing element, thereby determining the dosage amount to be dispensed, wherein the dosage amount is released by moving the releasing

element from a first stopper on a first side of the opening to a second stopper on a second side of the opening, opposite the first side.

Jacklich discloses a compact anesthetic syringe. As can be seen with reference to FIGS. 1 and 2, the syringe includes an operating handle 53 coupled to a ratchet 57, which is a separate pivotal piece. The separate ratchet 57 is pivoted on the handle 53 and a spring 55 biases the ratchet 57 into a groove 49. (*Jacklich, col. 2, lines 23 – 27*).

Jacklich does not disclose a releasing element for releasing a dosage amount to be dispensed by the injection device, wherein the releasing element projects radially outward from inside the casing through an opening in the casing of the injection device, and dimensions of the opening limit movement of the releasing element, thereby determining the dosage amount to be dispensed, wherein the dosage amount is released by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening, opposite the first side as recited in amended claim 17.

The Examiner likens the pawl 65 of Jacklich to the protrusion of amended claim 17 and the ratchet 57 of Jacklich to the releasing element of amended claim 17.

In the response to Applicant's arguments from the previous Office Action, the Examiner asserts that "the releasing element 57 is moved from a first stopper on a first side of the opening (the first side being above 65 in Figure 2) to a second stopper on a second side (49) of the opening." (*Office Action, page 7, lines 10-13*). However, the releasing element 57 would contact the pawl 65, itself, and could not move above pawl 65 to another side of the opening. (*See Jacklich, FIG. 2*).

Furthermore, Jacklich does not disclose that the releasing element projects radially outward from inside the casing through an opening in the casing of the injection device. As can be seen with reference to FIGS. 1 and 2, ratchet 57 of Jacklich extends at an acute angle from the operating handle 53, inward, engaging the ratchet teeth 63 of the piston rod 61.

Claim 19 depends directly from claim 17 and is patentable over Jacklich for at least those reasons set forth above with respect to amended claim 17.

Reconsideration and withdrawal of the § 102 rejection of claims 17 and 19 are requested.

Rejections under 35 U.S.C. § 103(a)

The rejections are traversed for at least the following reasons.

Jacklich in view of Ronvig

Claims 1-5 were rejected under 35 U.S.C. § 103(a) as unpatentable over Jacklich in view of Ronvig.

Jacklich is described above.

Amended claim 1 is directed to an injection device for administering a fluid product, comprising a casing, a piston rod for dispensing the fluid product from a product container, and operating means for operating said piston rod, said operating means being provided laterally on a circumferential surface of said casing, said operating means formed as a one-piece lever comprising a lever arm and a protrusion, the protrusion projected substantially perpendicular from the lever arm towards a longitudinal axis of the injection device and is fed into the casing, wherein the operating means is pivotable in a radial direction relative to the casing about a fulcrum and wherein the protrusion is co-operable with the distal end of the piston rod via a surface oblique relative to a longitudinal axis of the casing, such that by pivoting the lever arm of the operating means, movement of the protrusion along the oblique surface displaces the piston rod, thereby dispensing the fluid product from the product container.

Jacklich does not disclose or suggest an operating means formed as a one-piece lever comprising a lever arm and a protrusion, the protrusion projected substantially perpendicular from the lever arm towards a longitudinal axis of the injection device and is fed into the casing.

Instead, Jacklich discloses that the ratchet 57extends at an acute angle from the operating handle 53, engaging the ratchet teeth 63 of the piston rod 61. Also, as can be appreciated by reference to FIGS. 1 and 2, advancement of the piston rod 61 could not occur if the ratchet 57 extended from the operating handle 53 at any angle other than an acute angle. Specifically, advancement of the piston rod 61 could not occur if the ratchet 57 extended substantially perpendicular from the operating handle 53.

Furthermore, Jacklich does not disclose or suggest an operating means formed as a one-piece lever comprising a lever arm and a protrusion, the protrusion projected substantially perpendicular from the lever arm towards a longitudinal axis of the injection device and is fed into the casing, wherein the operating means is pivotable in a radial direction relative to the casing about a fulcrum and wherein the protrusion is co-operable with the distal end of the piston rod via a surface oblique relative to a longitudinal axis of the casing.

To the contrary, Jacklich discloses that the ratchet 57 actuates the piston rod 61 by contacting the ratchet teeth 63 along the sides of the piston rod. (*See Jacklich, FIG. 2*).

Ronvig fails to remedy the disclosure deficiencies of Jacklich as Ronvig does not disclose or suggest the features of amended claim 1.

Ronvig discloses a liquid dispenser with a U-shaped lever arm 22 with legs 23 that are substantially longer at the rear end than at the front end. At the rear end a latch 25 is provided between the legs 23, the latch is molded integrally with the lever arm. (*Ronvig, col. 3, lines 50-57*). The latch 25 engages with the teeth on the sides of toothed bar 20. (*See Ronvig, FIG. 2*).

Thus, Ronvig does not disclose that the operating means is pivotable in a radial direction relative to the casing about a fulcrum and wherein the protrusion is co-operable with the distal end of the piston rod via a surface oblique relative to a longitudinal axis of the casing as recited in amended claim 1.

Claims 2-5 depend directly from amended claim 1 and are patentable over the combination of Jacklich and Ronvig for at least those reasons set forth above with respect to amended claim 1.

Applicant requests that the rejection of claims 1-5 under § 103(a) over Jacklich in view of Ronvig be withdrawn.

Jacklich in view of Ronvig and further in view of Cosmai

Claim 8 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Jacklich and Ronvig as applied to claim 5 above, and further in view of Cosmai.

Jacklich and Ronvig are discussed above.

Claim 8 depends indirectly from amended claim 1 and is directed to the injection device of claims 1 and 5, wherein the "indicator comprises a scale up to a total number of dosage amounts contained in the product container and counts down by one unit on the scale when the piston rod or the operating means is operated."

As discussed above, the combination of Jacklich and Ronvig do not disclose the invention of amended claim 1, at least because neither Jacklich or Ronvig, alone or in combination, do not disclose an operating means that is pivotable in a radial direction relative to the casing about a fulcrum and wherein the protrusion is co-operable with the distal end of the piston rod via a surface oblique relative to a longitudinal axis of the casing.

Cosmai fails to remedy the fundamental disclosure deficiencies of Jacklich and Ronvig, as neither Cosmai nor Jacklich in combination with Ronvig disclose or suggest the features of amended claim 1.

Applicant requests, therefore, that the rejection of claim 8 under § 103(a) over Jacklich in view of Ronvig and further in view of Cosmai be withdrawn.

Conclusion

This response is being submitted on or before January 19, 2009, with the required fee for a two-month extension of time, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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